IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES,	)	C.A. No. 15-cv-13099-FDS (**Lead Case**)
Plaintiffs,	)	C.A. No. 21-cv-10598-FDS (Original Docket No.)
v.	)	
COLLEGIUM PHARMACEUTICAL, INC.,	)	**PUBLIC REDACTED VERSION**
Defendant.	)	

FIRST AMENDED COMPLAINT

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue" or "Plaintiffs"), for their First Amended Complaint against Collegium Pharmaceutical, Inc. ("Collegium" or "Defendant"), aver as follows:

NATURE OF THE ACTION

1. This is an action for relief from patent infringement, arising under the patent laws of the United States, Title 35, United States Code for infringement of U.S. Patent No. 10,407,434 ("the '434 patent"). This action relates to Collegium's Xtampza® ER oxycodone extended release capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg ("the Collegium NDA Products"). The Collegium NDA Products are the subject of and defined by Collegium's New Drug Application ("NDA") No. 208090 (including any amendments and/or supplements thereto, "Collegium's NDA"). Collegium submitted the Collegium NDA to the U.S. Food & Drug Administration ("FDA") under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), which sought approval to engage in the commercial manufacture, use, sale, offer for sale or importation of the Collegium NDA Products. The FDA approved the Collegium NDA and Collegium markets the Collegium NDA Products.

2. Plaintiffs seek judgment that Defendant has infringed the '434 patent. The '434 patent is listed in the FDA *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") as covering Purdue's OxyContin® (oxycodone hydrochloride) ("OxyContin"), an extended-release pain medication. Collegium has infringed the '434 patent (a) under 35 U.S.C. § 271(e)(2)(A) by filing the Collegium NDA on the Collegium NDA Products and (b) under 35 U.S.C. §§ 271(a), (b), (c), and (g) by actual marketing of the Collegium NDA Products.

3. The present action is related to currently-pending patent infringement actions Purdue previously filed against Collegium that also relate to the filing of Collegium's NDA and Collegium's marketing of the Collegium NDA Products. These previously-filed actions include Case No. 15-cv-13099-FDS ("the Lead Action"), in which Purdue has asserted infringement of U.S. Patent Nos. 9,073,933 ("the '933 patent") and 9,522,919 ("the '919 patent"), patents that are related to the '434 patent. The '434, '933, and '919 patents share, e.g., the same claim of priority, same inventors and same specification.

4. These previously-filed actions also include Case No. 17-cv-11814-FDS (the "'961 Patent Action"), in which Purdue has asserted infringement of U.S. Patent No. 9,693,961 ("the '961 patent"). The '961 Patent Action, which has been consolidated with the Lead Action for pretrial purposes, is related to the present action in that, *inter alia*, they both involve the same infringing product, the Collegium NDA Products.

5. Purdue and Collegium agreed and stipulated to consolidate the present action with the Lead Action for case management, discovery, and pretrial purposes, which the Court granted. (21-cv-10598, D.I. 6; 15-cv-13099, D.I. 264.)

THE PARTIES

6. Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue Pharma is an owner of the '434 patent. Purdue Pharma is also the holder of NDA No. 022272 for the extended-release oxycodone pain-relief medication OxyContin and is involved in the sale of OxyContin in the United States.

7. Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the '434 patent, and is involved in the manufacture of OxyContin.

8. Rhodes Technologies ("Rhodes") is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of the '434 patent, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin.

9. Upon information and belief, Collegium is a corporation organized and existing under the laws of the Commonwealth of Virginia, having its principal place of business at 780 Dedham Street, Suite 800, Canton, MA 02021.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, including 35 U.S.C. § 271.

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Collegium, and venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b), because Collegium has its principal place of business in this Judicial District.

13. Collegium is in the business of preparing pharmaceuticals that it distributes in the Commonwealth of Massachusetts and throughout the United States.

14. Upon information and belief, once Collegium's NDA was approved, the Collegium NDA Products were, among other things, marketed and distributed in Massachusetts, and/or prescribed by physicians practicing and dispensed by pharmacies located within Massachusetts, all of which have a substantial effect on Massachusetts.

THE '434 PATENT

15. The Orange Book identifies drug products that have been approved by the FDA under the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.). The Orange Book also provides a listing of certain patents that cover a given drug product or the use thereof.

16. Purdue is the lawful owner of all right, title, and interest in the '434 patent, entitled "PROCESS FOR PREPARING OXYCODONE COMPOSITIONS," including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering the drug OxyContin, which is the subject of approved NDA No. 022272. The '434 patent was duly and legally issued on September 10, 2019, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors. A copy of the '434 patent is attached as Exhibit A.

COLLEGIUM'S NDA

17. Upon information and belief, Collegium submitted Collegium's NDA to the FDA under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)),

seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Collegium NDA Products.

18. On or about April 26, 2016, the FDA approved Collegium's NDA based on Collegium's filings as of that date.

19. On June 20, 2016, Collegium issued a press release announcing the commercial launch of the Collegium NDA Products.

20. Collegium has begun commercial manufacture of the Collegium NDA Products, has begun offering for sale and selling the Collegium NDA Products, and continues to manufacture (or have manufactured), offer for sale, sell, and distribute the Collegium NDA Products, including in this district.

21. After having already begun marketing the Collegium NDA Products, on or about October 4, 2016, Collegium filed a supplemental application relating to Collegium's NDA ("Collegium's 2016 sNDA"). On or about November 6, 2017, the FDA approved Collegium's 2016 sNDA. On information and belief, Collegium has marketed the Collegium NDA Products according to Collegium's 2016 sNDA

22. Collegium has filed additional supplemental applications relating to Collegium's NDA. For example, on or about August 14, 2020 and after the '434 patent issued, Collegium filed a supplemental application relating to Collegium's NDA ("Collegium's 2020 sNDA") On or about March 4, 2021, the FDA approved Collegium's 2020 sNDA. On information and belief, Collegium has marketed the Collegium NDA Products according to Collegium's 2020 sNDA.

23. Collegium is the owner of Collegium's NDA, including any and all supplements thereto.

CLAIMS FOR RELIEF:

COUNT I
(Collegium's Filing of Its NDA Constitutes Infringement of the '434 Patent)

24. Purdue incorporates by reference and realleges paragraphs 1-23 above as though fully restated herein.

25. Collegium's submission of its NDA for a drug claimed in the '434 patent was an act of infringement under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

26. Further, Collegium's submission of Collegium's 2020 sNDA for a drug claimed in the '434 patent was an act of infringement under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A). *See Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1127 (Fed. Cir. 2018) ("There is no support for the proposition that the question of infringement must be addressed solely based on the initial ANDA filing, given that the statute contemplates that the ANDA will be amended as a matter of course. Thus, amendments to an ANDA, including a Paragraph IV certification for a later-issued patent, can constitute an act of infringement under § 271(e)(2)(A)").

27. Upon information and belief, the Collegium NDA Products use or, according to Collegium, contain oxycodone base. The oxycodone base and the process by which the oxycodone base is made is covered by one or more claims of the '434 patent, including but not limited to at least claims 1-7, 9, 13-15, 17, and 19, which recite, *inter alia*, a process of purifying oxycodone free base or oxycodone HCl that contains 8α,14-dihydroxy-7,8-dihydrocodeinone; a process of purifying oxycodone free base or oxycodone HCl that contains 8α,14-dihydroxy-7,8-dihydrocodeinone, wherein the ratio of 8α, 14-dihydroxy-7,8-dihydrocodeinone or HCl salt thereof to oxycodone free base or oxycodone HCl following step (i) is 0.04% or less as measured by HPLC; and purified oxycodone free base prepared according to such processes, wherein the

ratio of 8α, 14-dihydroxy-7,8-dihydrocodeinone to oxycodone free base is 0.04% or less as measured by HPLC.

28. For example, upon information and belief, the oxycodone base used in the Collegium NDA Products is made according to the process of independent claim 1 of the '434 patent. Claim 1 of the '434 patent recites: "A process of purifying oxycodone free base or oxycodone HCl that contains 8α,14-dihydroxy-7,8-dihydrocodeinone or HCl salt thereof, said process comprising:

(ii) reducing the amount of 8α,14-dihydroxy-7,8-dihydrocodeinone or HCl salt thereof in the oxycodone free base or oxycodone HCl;

(ii) dissolving the resultant oxycodone free base or oxycodone HCl from step (i) in a suitable recrystallization solvent;

(iii) cooling the recrystallization solvent to precipitate purified oxycodone free base or oxycodone HCl; and

(iv) recovering the purified oxycodone free base or oxycodone HCl.

29. [redacted]

30. [redacted]

Purdue Pharma L.P. v. Teva Pharms., USA, Inc. (*In re Oxycontin Antitrust Litig*.), 994 F. Supp. 2d 367, 392 (S.D.N.Y. 2014). (*Compare* COLL0014913–14, NORCOL000004–15 *with In re OxyContin*, 994 F. Supp. 2d at 391–93.) As the *In re OxyContin* Court found, [redacted]

[redacted]

31. [redacted]

[redacted]

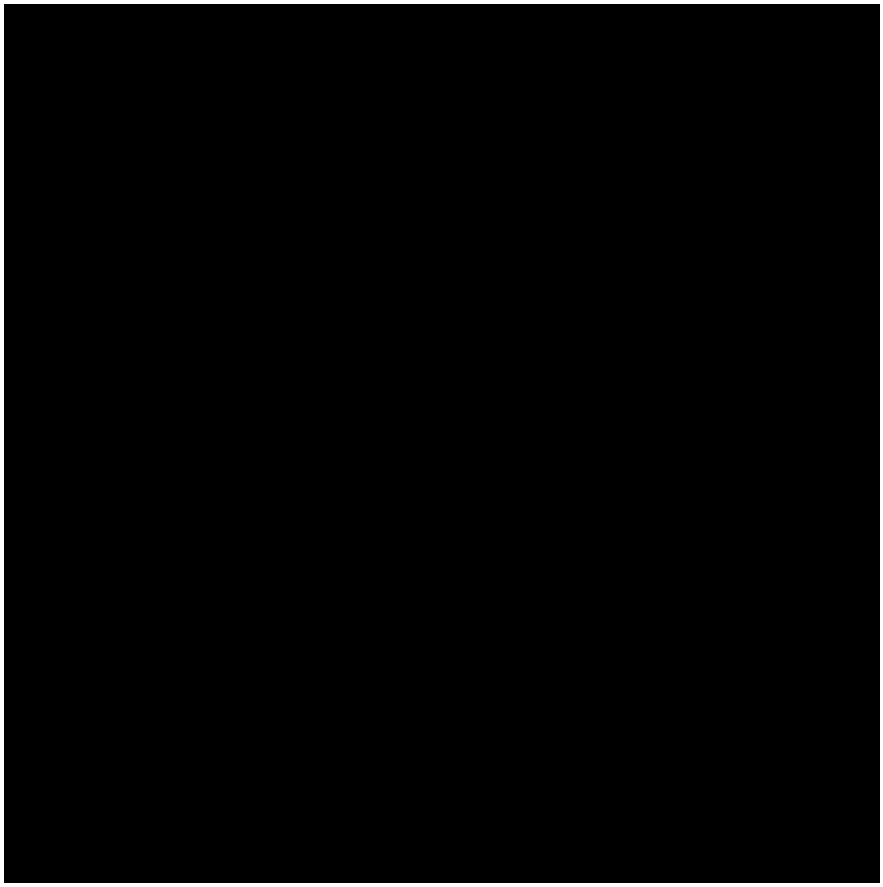
393-[redacted]

[redacted]

14-[redacted]

[redacted]

[1] All documents with production numbers cited herein have been produced or deemed produced in the Lead Action, and are available to Collegium.



32. Claim 1 is infringed by performing each step of the Noramco process.

33. [redacted]

34. [redacted]

35. [redacted]

[redacted]

36. In addition, upon information and belief, the oxycodone base used in the Collegium NDA Products is made according to the process of claim 2 of the '434 patent. Claim 2 of the '434 patent recites: "The process of claim 1, wherein the ratio of 8α, 14-dihydroxy-7,8-dihydrocodeinone or HCl salt thereof to oxycodone free base or oxycodone HCl following step (i) is 0.04% or less as measured by HPLC."

37. [redacted] and thus infringes, claim 2.

38. Further, Collegium has represented to this Court that the Collegium NDA Products contain oxycodone base. Specifically, Collegium has stated that "[t]he API, or drug substance, in XTAMPZA® ER is oxycodone base, not oxycodone myristate." Defendant Collegium Pharmaceutical, Inc.'s Local Rule 56.1 Statement Of Material Facts As To Which

There Is No Genuine Issue To Be Tried, No. 15-cv-13099, D.I. 108-2 ¶ 66. In addition, Collegium has represented to this Court that "[t]he XTAMPZA® ER microspheres contain oxycodone base, myristic acid, yellow beeswax, carnauba wax, and stearoyl polyoxyl-32 glycerides." *Id.* ¶ 18.

39. Further, upon information and belief, the oxycodone base used in the Collegium NDA Products use and/or contain the purified oxycodone base covered by claim 19 of the '434 patent. Claim 19 of the '434 patent recites: "Purified oxycodone free base prepared according to the process of claim 2, wherein the ratio of 8α, 14-dihydroxy-7,8-dihydrocodeinone to oxycodone free base is 0.04% or less as measured by HPLC." [redacted] meets the requirements of claim 19.

40. Collegium without authority uses, offers to sell or sells in the United States the Collegium NDA products that use or, according to Collegium, contain the purified oxycodone base covered by claim 19 of the '434 patent. Thus, Collegium is liable for infringement under 35 U.S.C. § 271(a).

41. Upon information and belief, Collegium's commercial manufacture, use, sale, offer for sale, and/or importation of the oxycodone base and/or the Collegium NDA Products using the claimed oxycodone base has infringed, contributed to the infringement of, and/or induced the infringement of one or more claims of the '434 patent under 35 U.S.C. §§ 271(a), (b), (c), and (g).

42. The marketing materials, and/or the labeling associated with the Collegium NDA Products, including, but not limited to, any package inserts, medication guides, full prescribing information, or other materials related to such labeling, instructs healthcare

providers and patients to use the oxycodone base from the Collegium NDA Products made according to the process of one or more claims of the '434 patent, thereby infringing the asserted claims. Collegium intends to cause infringement of the '434 patent and has knowledge that the use of the Collegium NDA Products according to Collegium's instructions causes direct infringement of the '434 patent under 35 U.S.C. § 271(g) by healthcare providers, physicians, other medical care workers, patients, and any other persons using the Collegium NDA Products. *See Genentech, Inc. v. Amgen Inc*., No. 17-cv-1407-CFC, 2020 WL 708433, at *2 (D. Del. Feb. 12, 2020) ("[I]mportation is not required to establish infringement liability under § 271(g)".); *Zoltek Corp. v. United States*, 672 F.3d 1309, 1315 (Fed. Cir. 2012)("271(g) . . . is meant to give relief to process patent holders when the resulting products of their patented process are used within the United States—regardless of where the process is practiced"). Thus, Collegium is liable for inducing infringement under 35 U.S.C. § 271(b) of those using the Collegium NDA Products.

43. Further, Collegium uses Patheon Pharmaceuticals Inc. ("Patheon") as a contract manufacturer to make the Collegium NDA Products. *See Purdue Pharma L.P. et al., v. Collegium Pharmaceutical, Inc*., 15-cv-13099-FDS, D.I. 193 at 13 (Sept. 28, 2018).

44. Patheon makes the Collegium NDA Products using specifications and instructions from Collegium, including specification and manufacturing parameters set forth in Collegium's NDA.

45. Patheon uses oxycodone base to make the Collegium NDA Products and makes the Collegium NDA Products in the United States.

46. In making the Collegium NDA Products that will be used, offered for sale or sold under Collegium's NDA, Patheon must follow the manufacturing parameters set forth

in Collegium's NDA. *See* 21 U.S.C. 355(a); 21 U.S.C. 331(d); 21 C.F.R. 314.410(c). Thus, Patheon makes the Collegium NDA Products under Collegium's direction and control.

47. Accordingly, Collegium's contract manufacturer, Patheon, under Collegium's direction and control and pursuant to Collegium's specifications and instructions, including specification and processes set forth in Collegium's NDA, uses the purified oxycodone base covered by claim 19 of the '434 patent to make the Collegium NDA Products. Thus, Collegium is directly liable for Patheon's infringement of claim 19 of the '434 patent under 35 U.S.C. § 271(a).

48. In addition, those manufacturing and/or using the oxycodone base used in the manufacture of the Collegium NDA Products pursuant to Collegium's specifications, including Collegium's NDA specifications and instructions, including but not limited to, for example, Noramco and/or Patheon, directly infringe one or more of at least claims 1-7, 9, 13-15, 17 and 19 of the '434 patent. Collegium intends to cause infringement of the '434 patent and has knowledge that manufacturing of the oxycodone base used in the Collegium NDA Products and/or the Collegium NDA Products according to Collegium's instructions and NDA specifications causes direct infringement of the '434 patent by manufacturers. Thus, upon information and belief, Collegium is liable for inducing infringement under 35 U.S.C. § 271(b) of those manufacturing the oxycodone base used in the Collegium NDA Products and/or the Collegium NDA Products.

49. The oxycodone base used in the Collegium NDA Products constitutes a material part of the inventions covered by the claims of the '434 patent, is especially made or adapted to infringe the asserted claims, and there are no substantial non-infringing uses for the oxycodone base used in Collegium NDA Products. Thus, Collegium is liable for contributory infringement under 35 U.S.C. § 271(c).

50. Collegium without authority offers to sell, sells or uses within the United States the Collegium NDA Products that use, or according to Collegium, contain oxycodone base made by a process covered by at least claims 1-7, 9, 13-15 and 17 of the '434 patent.

51. Based upon knowledge of Noramco's oxycodone process and documents produced in the Lead Action, Noramco performs all the steps of at least claims 1-7, 9, 13-15 and 17 of the '434 patent.

52. Upon information and belief, the oxycodone base used in the Collegium NDA Products, and the process intermediates of the oxycodone base of Noramco's process, meets the 8α ratio claim element contained in certain dependent claims.

53. Further, the oxycodone base covered by the claims of the '434 patent is not materially changed by subsequent processes, including formulation into the Collegium NDA Products and is not a trivial and nonessential component of the Collegium NDA Products. Thus, Collegium is directly liable for infringement under 35 U.S.C. § 271(g). *See Eli Lilly & Co. v. American Cyanamid Co*., 82 F.3d 1568, 1573 (Fed. Cir. 1996) ("In the chemical context, a 'material' change in a compound is most naturally viewed as a significant change in the compound's structure and properties.")

54. Collegium without authority uses within the United States the oxycodone base made by a process covered by at least claims 1-7, 9, 13-15 and 17 of the '434 patent. Specifically, Collegium's contract manufacturer, Patheon, under Collegium's direction and control and pursuant to Collegium's specifications and instructions, including specification and processes set forth in Collegium's NDA, uses the oxycodone base covered by at least claims 1-7, 9, 13-15 and 17 of the '434 patent to make the Collegium NDA Products.

55. Further, the oxycodone base covered by the claims of the '434 patent is not materially changed by subsequent processes, including formulation into the Collegium NDA Products and is not a trivial and nonessential component of the Collegium NDA Products. Thus, Collegium is directly liable for Patheon's direct infringement of at least claims 1-7, 9, 13-15 and 17 of the '434 patent under 35 U.S.C. § 271(g). *See Genentech*, 2020 WL 708433, at *2 ("[I]mportation is not required to establish infringement liability under § 271(g)".); *Zoltek*, 672 F.3d at 1315 ("271(g) . . . is meant to give relief to process patent holders when the resulting products of their patented process are used within the United States—regardless of where the process is practiced").

COUNT II
(Collegium's Marketing of the Collegium NDA Products Infringes and Has Infringed the '434 Patent)

56. Purdue incorporates by reference and realleges paragraphs 1-55 above as though fully restated herein.

57. Upon information and belief, Collegium has begun commercial manufacture of the Collegium NDA Products, began offering for sale and selling the Collegium NDA Products, and continues to manufacture (or have manufactured), offer for sale, sell, and distribute the Collegium NDA Products.

58. Since at least the issue date of the '434 patent, Collegium has been infringing the '434 patent by making, using, offering for sale, selling, and distributing products embodying the patented inventions in violation of 35 U.S.C. § 271(a) and (g), inducing others to make, use, sell, or offer for sale products and methods embodying the patented inventions in violation of 35 U.S.C. § 271(b), and/or by contributing to the manufacture, use, sale, or offer for sale of products embodying the patented inventions in violation of 35 U.S.C. § 271(c).

59. Collegium's infringement of the '434 patent has been willful, egregious, and in disregard of the '434 patent.

60. Collegium has had knowledge of the '434 patent at or around the date of issuance of the '434 patent, and no later than October 30, 2020.

61. By the issue date of the '434 patent or by at least October 30, 2020, Collegium has had knowledge that it had no good-faith non-infringement and invalidity positions regarding the '434 patent.

62. Purdue has been and will continue to be substantially and irreparably damaged and harmed by Collegium's manufacture, use, sale, or offer for sale of the Collegium NDA Products if such infringement is not enjoined. Purdue does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Purdue prays for judgment:

A. Adjudging that Collegium has infringed, and that Collegium's commercial sale, offer for sale, use, manufacture, and/or importation of the Collegium NDA Products has infringed, induced infringement of, and/or contributed to the infringement of the '434 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Collegium's NDA, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), to be a date not earlier than the date of expiration of the '434 patent, plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Collegium, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns,

from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '434 patent;

D. Awarding, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, damages to Purdue resulting from Collegium's commercial manufacture, use, importation into the United States, offer for sale, or sale of the Collegium NDA Products prior to the expiration of the '434 patent, increased to treble the amount found or assessed, together with interest;

E. Declaring this an exceptional case and awarding Purdue its attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

F. Awarding Purdue such other and further relief as this Court may deem just and proper.

Dated: May 21, 2021

/s/ Christopher M. Morrison

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CERTIFICATE OF SERVICE

I, Christopher M. Morrison, hereby certify that I have on this 21 day of May 2021 filed a copy of the foregoing through the Court's CM/ECF system, which will serve an electronic copy on counsel of record identified in the Notice of Electronic Filing.

/s/ Christopher M. Morrison